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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/723,722	11/28/2000	John P. Anderson	00228-US-NEW2C1	9856

21835 7590 07/01/2002

ELAN PHARMACEUTICALS, INC.  
INTELLECTUAL PROPERTY DEPARTMENT  
800 GATEWAY BOULEVARD  
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/723,722

Applicant(s)

ANDERSON ET AL.

Examiner

Celine Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-131 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-131 are pending in the application.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-22 and 37-53, drawn to an isolated  $\beta$ -secretase, classified in class 435, subclass 183.
- II. Claims 23-36, drawn to a  $\beta$ -secretase crystalline composition comprising said  $\beta$ -secretase and an inhibitor, classified in class 530, subclass 402.
- III. Claims 23-31, drawn to a  $\beta$ -secretase crystalline composition comprising said  $\beta$ -secretase and a substrate, classified in class 530, subclass 402.
- IV. Claims 54 and 55, drawn to an antibody to  $\beta$ -secretase, classified in class 530, subclass 387.1.
- V. Claims 56-67, drawn to a nucleic acid encoding a  $\beta$ -secretase, a vector comprising said nucleic acid and a cell comprising said vector, classified in class 435, subclass 320.1.
- VI. Claims 68-72, drawn to a method of making  $\beta$ -secretase recombinantly, classified in class 435, subclass 69.1.
- VII. Claims 73-77, drawn to a cell comprising a first nucleic acid encoding a  $\beta$ -secretase and a second nucleic acid encoding a  $\beta$ -secretase substrate, classified in class 435, subclass 325.

- VIII. Claims 78-80, 84 and 85, drawn to a method of screening for compounds that inhibit A $\beta$  production in vitro, classified in class 424, subclass 93.1.
- IX. Claims 78 and 81, drawn to a method of screening for compounds that inhibit A $\beta$  production in vivo, classified in class 800, subclass 9.
- X. Claims 78 and 81-83, drawn to a method of screening for compounds that inhibit A $\beta$  production using a transgenic animal, classified in class 800, subclass 3.
- XI. Claims 86-90, drawn to a method of screening for compounds that inhibit A $\beta$  production by measuring the binding of  $\beta$ -secretase to its inhibitor in presence of a test compound, classified in class 536, subclass 24.5.
- XII. Claims 91-103, drawn to a  $\beta$ -secretase inhibitor, classified in class 530, subclass 300.
- XIII. Claims 104-107, drawn to a screening kit, classified in class 435, subclass 183.
- XIV. Claims 108-111 and 126, drawn to a  $\beta$ -secretase knockout mouse, classified in class 800, subclass 18.
- XV. Claims 112 and 113, drawn to a method screening drugs effective in treating Alzheimer's disease in vivo, classified in class 800, subclass 3.
- XVI. Claims 114 and 115, drawn to a method of treating a patient having a predilection for Alzheimer's disease, classified in class 514, subclass 44.
- XVII. Claims 116 and 117, drawn to a method of inhibiting proteolysis of APP to A $\beta$  in a tissue, classified in class 424, subclass 130.1.
- XVIII. Claims 118-119, drawn to a drug for treating Alzheimer's disease, classified in class 536, subclass 24.5.

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XIX. Claims 121-125, drawn to a method of diagnosing the presence of a predilection for Alzheimer's disease, classified in class 536, subclass 24.31.

XX. Claims 127-131, drawn to a method of purifying  $\beta$ -secretase with an affinity column, classified in class 530, subclass 412.

The inventions are patentably distinct, each from the other for the following reasons.

The inventions of Group I-V, VII, XII-XIV and XVIII are patentably distinct, each from the other because the inventions are drawn to materially different compositions. Each composition is structurally, biologically and functionally different from each other, and a search of all the above groups is not co-extensive.

The inventions of Groups VI, VIII-XI, XV-XVII, XIX and XX are patentably distinct, each from the other because the inventions are drawn to methods that require different starting materials or modes of operation. Each method involves different steps. Therefore, the inventions are patentably distinct, and a search of all the groups is not co-extensive.

Inventions I and VI and XX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product of Group I can be made recombinantly or by protein purification. Therefore, the invention of Group I and VI and XX are patentably distinct.

Inventions I and VIII-XI, XV-XVII and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

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product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in different methods as claimed in Groups VIII-XI, XV-XVII and XIX. Therefore, the invention of Group I is patentably distinct from the inventions of Groups VIII-XI, XV-XVII and XIX.

Inventions of Groups II-V, VII, XII-XIV and XVIII are patentably distinct from the inventions of Groups II-V, VII, XII-XIV and XVIII because the inventions are drawn to compositions and methods that are not directly related. All the compositions of the above groups can be used in methods other than those claimed in Groups VI, VIII-XI, XV-XVII, XIX and XX. Therefore, the inventions of Groups II-V, VII, XII-XIV and XVIII are patentably distinct from the inventions of Groups II-V, VII, XII-XIV and XVIII.

Because these inventions are distinct for the reasons given, they have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for each group is not co-extensive. Therefore, there is a burden to search all the groups. As such, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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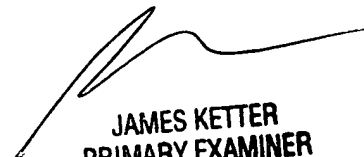
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

June 28, 2002



JAMES KETTER  
PRIMARY EXAMINER